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Comments on EPA's "Aquatic Biota Tissue TRV Derivation" for Portland Harbor by Jennifer Peterson, Oregon DEQ

Objectives:

I think it is particularly important for any distribution statistical method to be absolutely clear how the proposed statistical analysis will meet the stated objectives, which in this case are the assessment endpoints. Objectives that are important here are how the proposal relates back to the species we are trying to protect and at what level of protection (individual, population or community). Based on these objectives, the data used for TRV derivation would be very different. For example, are you trying to come up with a robust community TRV number that would be protecting a large (e.g. 95%) percentage of the community, or is the objective to better represent data for one species (e.g. clams or salmonids). I think it should be both, and I am not sure that is part of the current proposal.

For the community approach, it would be important to select representative TRVs of different populations (species) of the community. For fish communities, this would involve endpoint TRVs (growth, survival and reproduction) for different fish species, representing populations in the community. In this case, it would be important to carefully select representative species TRVs for each appropriate family classification (e.g. coldwater fish like salmonids and trout; catfish, etc.), and then calculate a SSD. However, in some applications of an SSD calculation, this would result in not protecting a certain percentage of the species (or populations) that make up a community. Therefore, this approach may not work in the case where we are explicitly protecting a specific species of fish, (e.g. T&E species such as salmonids), that may happen to fall within the 5^{th} or 10^{th} percentile of the group not protected. In this case, I would advocate compiling the literature on that species separately and use a distribution (or other TRV derivation method) to select an appropriate threshold value *protective of that species*.

It is unclear from the document which approach we are taking and why, but I think they should link back to the assessment endpoints. Cases where we pulled out specific populations for protection because of cultural or societal importance should have a preference for the species specific SSD approach (e.g. salmonids, clams, crayfish). Cases where we are protecting fish guilds (e.g. carp and sucker) it is more appropriate to pool sensitivity data from multiple species for the SSD. Now it may be that salmonids (and trout) are still represented in the community analysis as on species in the distribution but I don't think you can assume that because they are included in that wider analysis that you are calculating TRVs protective of those species. The separate analysis needs to be done to ensure this is the case.

Level of Protection:

Another important issue that ties back to assessment endpoints is the level of protection. For example, we may decide to do clam and salmonid species specific distributions for

the reasons stated above. However, these two species are afforded different levels of protection in the risk assessment. Therefore, it is appropriate to pull from two different thresholds from the literature – NOERs for T&E species and LOERs for population level assessments. This distinction is not made in your paper. Instead, it appears that two different percentiles (5^{th} and 10^{th}) *of the LOER* distributions are proposed for use for species protected at the individual and population level, respectively. It is unclear if this proposal is supported by the literature, or if it would be appropriately protective of the stated assessment endpoints. I think it is more technically defensible to use NOER or LOER distributions depending for individual or population level or protection, both at the 95^{th} percentile.

Species and Sensitivity Representation:

For protection at the community level, each species in the community needs to be appropriately represented with equal weight in the distribution. For example, would you run the SDD if five of the papers are on a warm water fish species? How would you represent the sensitivity of other coldwater fish species (e.g. trout)? What are the minimum requirements for the SSD to be appropriate in terms of representativeness and feedback to the assessment endpoints?

I am also confused on how you will deal with multiple endpoints and multiple species. The text states "multiple tox endpoint LOERs for the same species will be used to incorporate the LOER for each available endpoint for each species in the final SSD. This approach may result in one, two, or three LOERs for a given species within the SSD for a given chemical". If you aren't going to calculate separate SSDs for the different endpoints represented by different species (which in some cases may be preferred since it gives more info) then it seems like you would have to include the most sensitive endpoint for each representative species *one time*.

Paper Selection:

Once the objectives are clearly outlined, I think we have to have to have criteria for paper inclusion. I don't think the SSD approach will avoid the paper selection arguments altogether. For example, if you have five papers that are of questionable quality and one really good paper, and you run a SSD to come up with a TRV does that make it a better number? Maybe not – esp. if the distribution is driven by the other papers. I think this will be less important where we have more papers available for the analysis.

SSD Distribution Calculation:

Basing a SDD on only 5 papers may have a lot of uncertainty associated with it and may not be an improvement on selecting one high quality paper. In DEQ's bioaccumulation guidance, we used SSD methodology to calculate tissue TRVs for fish. However, the required data set was at least four acceptable NOER/LOER pairs based on unique species. Confidence bounds were calculated and used based on the 95% level of significance, corresponding to 95 percent species protection. Was this method considered? Were the statistics evaluated to determine which SSD method would meet the assessment endpoint with the highest level of confidence?

Uncertainty Factor Approach:

I think uncertainty factors can be appropriately applied to toxicity data. There is a lot of precedent for this, and is sometimes downright required (e.g. HH). I think we can come up with reasonable uncertainty factors – I am not sure we would ever see a 1000 fold factor.

Lowest Value Approach:

I would not select a mean for a given species, because it does not appropriately give weight to the more appropriate studies. I would advocate selecting the most appropriate study (with uncertainty factors), and then discussing uncertainty with the approach in the uncertainty section. Certainly bounds on the appropriateness of the value can be gleaned based on where the value falls relative to other aquatic species. Uncertainty factors should be used, and this has also been EPA's comment on the issue to date. EPA Region 10 Supplemental Ecological Risk Assessment Guidance for Superfund specifies uncertainty factors if needed. This approach is supported by decades of toxicology and risk assessments. This is also one line of evidence that will be evaluated – there is uncertainty associated with them all.

Derivation Procedures:

NOER Exclusion: We shouldn't be excluding NOERs for the reasons already stated (e.g. level of protection and assessment endpoints). Granted, there may be problems with some NOER data where concentration breaks in testing determine the NOER. However, this can somewhat be avoided by selecting good papers, and you are not ignoring potentially good toxicological information for the selection of TRVs. The way this was dealt with in the past was EPA stating that the LWG should select the NOER and LOER from the same paper. LWG agreed to this methodology.

Tox Data Weighting: If tox data (e.g. LOERs) are to have equal weight, the selection process for inclusion must be appropriate and well thought out.

Percentile Selection: The use of the 5^{th} and 10^{th} percentile of the LOER data is not justified. Is there more info to help understand the rational for selection?

Survival LOERs: Where does the factor of 2.27 come from? I am not sure it would always be appropriate to weight them the same as growth and reproduction after application of the factor.

Chemicals for Derivation:

PAHs are identified as contaminants for which "generally applicable tissue TRVs" should not be derived, because of differences in metabolic transformation. While I agree, I also think if there are residue effect levels for the species collected in Portland Harbor (e.g. clams and crayfish) I think we can develop TRVs for PAHs. It is o.k. if they do not apply to other invertebrate species. PAHs are a group of chemicals for which we could use more lines of evidence.